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weight per day (22 milligrams per kilogram) for 5 days.

(ii) *Indications for use.* For the control of mortality associated with *E. coli* organisms susceptible to neomycin sulfate in growing turkeys.

(iii) *Limitations.* Add to drinking water; not for use in liquid supplements. Prepare a fresh solution daily. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 5 consecutive days.

[64 FR 31497, June 11, 1999, as amended at 66 FR 14073, Mar. 9, 2001; 67 FR 72366, Dec. 5, 2002; 67 FR 78971, Dec. 27, 2002; 68 FR 4914, Jan. 31, 2003]

§ 520.1485 Neomycin sulfate oral solution.

(a) *Specifications.* Each milliliter contains 200 milligrams of neomycin sulfate (equivalent to 140 milligrams of neomycin base).

(b) *Sponsors.* See Nos. 000009, 051259, and 059130 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.430 of this chapter.

(d) *Conditions of use*—(1) *Amount.* 10 milligrams of neomycin sulfate per pound of body weight per day in divided doses for a maximum of 14 days.

(2) *Indications for use.* For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin in cattle (excluding veal calves), swine, sheep, and goats.

(3) *Limitations.* Administer undiluted or in drinking water. Prepare a fresh solution daily. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days. Discontinue treatment prior to slaughter as follows: 1 day for cattle, 2 days for sheep, and 3 days for swine and goats.

[58 FR 38972, July 21, 1993, as amended at 60 FR 3079, Jan. 13, 1995; 61 FR 31398, June 20, 1996; 62 FR 60657, Nov. 12, 1997; 63 FR 45944, Aug. 28, 1998; 65 FR 45877, July 26, 2000; 65 FR 53581, Sept. 5, 2000]

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§ 520.1498 Nitazoxanide paste.

(a) *Specifications.* Each milligram (mg) of paste contains 0.32 mg nitazoxanide.

(b) *Sponsor.* See No. 065274 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* On days 1 through 5, administer 11.36 mg per pound (lb) body weight; on days 6 through 28, administer 22.72 mg/lb body weight.

(2) *Indications for use*—For the treatment of equine protozoal myeloencephalitis (EPM) caused by *Sarcocystis neurona*.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 500, Jan. 6, 2004]

§ 520.1510 Nitenpyram tablets.

(a) *Specifications.* Each tablet contains 11.4 or 57 milligrams (mg) nitenpyram.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Special considerations.* The concurrent use of nitenpyram tablets and flavored milbemycin/lufenuron tablets as in paragraph (d)(1)(ii)(B) of this section shall be by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*—(A) One 11.4-mg tablet for dogs weighing less than 25 pounds (lb) or one 57-mg tablet for dogs weighing more than 25 lb, as needed, for use as in paragraph (d)(1)(ii)(A) of this section.

(B) One 11.4-mg tablet for dogs weighing less than 25 lb or one 57 mg tablet for dogs weighing more than 25 lbs, once or twice weekly, for use as in paragraph (d)(1)(ii)(B) of this section.

(ii) *Indications for use*—(A) For the treatment of flea infestations on dogs and puppies 4 weeks of age and older and 2 lbs of body weight or greater.

(B) The concurrent use of nitenpyram tablets as in paragraph (d)(1)(i)(B) of this section with either flavored lufenuron tablets as in § 520.1288(c)(1) of this chapter or flavored milbemycin and lufenuron tablets as in § 520.1446(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

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(2) *Cats*—(i) *Amount*—(A) One 11.4-mg tablet, as needed, for use as in paragraph (d)(2)(ii)(A) of this section.

(B) One 11.4-mg tablet, once or twice weekly, for use as in paragraph (d)(2)(ii)(B) of this section.

(ii) *Indications for use*—(A) For the treatment of flea infestations on cats and kittens 4 weeks of age and older and 2 lbs of body weight or greater.

(B) The concurrent use of nitenpyram tablets as in paragraph (d)(2)(i)(B) of this section with flavored lufenuron tablets as in § 520.1288(c)(2) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

[68 FR 51906, Aug. 29, 2003]

§ 520.1615 Omeprazole.

(a) *Specifications*. Each gram of paste contains 0.37 gram omeprazole.

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Special considerations*. When labeled for use as in paragraph (d)(2)(i) of this section, product labeling shall bear: “Federal law restricts this drug to use by or on the order of a licensed veterinarian.”

(d) *Conditions of use in horses*—(1) *Amount*—(i) For treatment of gastric ulcers, 1.8 milligrams per pound (mg/lb) of body weight (4 milligrams per kilogram (mg/kg)) once daily for 4 weeks. For prevention of recurrence of gastric ulcers, 0.9 mg/lb of body weight (2 mg/kg) once daily for at least an additional 4 weeks.

(ii) For prevention of gastric ulcers using the premarked syringe, one dose per day for up to 28 days. Each dose delivers at least 1 mg/kg of body weight. Horses over 1,200 lb body weight should receive two doses per day.

(2) *Indications for use*. (i) For treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older.

(ii) For prevention of gastric ulcers in horses.

(3) *Limitations*. Do not use in horses intended for human consumption.

[69 FR 13220, Mar. 22, 2004]

§ 520.1616 Orbifloxacin tablets.

(a) *Specifications*. Each tablet contains 5.7, 22.7, or 68 milligrams of orbifloxacin.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount*. 2.5 to 7.5 milligrams per kilogram body weight.

(ii) *Indications for use*. For management of diseases associated with bacteria susceptible to orbifloxacin.

(iii) *Limitations*. Administer orally once daily for 2 to 3 days beyond cessation of clinical signs for up to a maximum of 30 days. If no improvement is seen within 5 days, diagnosis should be reevaluated and a different course of therapy considered. Orbifloxacin is contraindicated in immature dogs and cats during the rapid growth phase. Orbifloxacin and other quinolones have been shown to cause arthropathy in immature animals of most species. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[62 FR 29012, May 29, 1997, as amended at 62 FR 61627, Nov. 19, 1997]

§ 520.1628 Oxfendazole powder and pellets.

(a) *Specifications*—(1) *Powder for suspension*. Each gram of powder contains 7.57 percent oxfendazole.

(2) *Pellets*. Each gram of pellets contains 6.49 percent oxfendazole.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 10 milligrams per kilogram of body weight.

(2) *Indications for use*. The drug is used in horses for removal of the following gastrointestinal worms: Large roundworms (*Parascaris equorum*), mature and immature pinworms (*Oxyuris equi*), large strongyles (*Strongylus edentatus*, *Strongylus vulgaris*, and *Strongylus equinus*), and small strongyles.

(3) *Limitations*—(i) *Powder for suspension*. For gravity administration via stomach tube or for positive administration via stomach tube and dose syringe. Discard unused portions of suspension after 24 hours. Mix drug according to directions prior to use. Administer drug with caution to sick or debilitated horses. Not for use in horses intended for food. Federal law